PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference srt.1886.pct.nm/cr.d	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 03/03802	International filing date *(day/month/year)* 01.09.2003	Priority date *(day/month/year)* 31.08.2002
International Patent Classification (IPC) or both national classification and IPC C08G18/10		
Applicant OCUTEC et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the opinion
   II ☐ Priority
   III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   IV ☐ Lack of unity of invention
   V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   VI ☐ Certain documents cited
   VII ☐ Certain defects in the international application
   VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
31.03.2004	10.12.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Kairi, M Telephone No. +49 89 2399-8672

Form PCT/IPEA/409 (Cover Sheet) (January 2004)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/03802

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-29 as originally filed

Claims, Numbers

1-40 as originally filed

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	4-7,10,12-17,19-27,30,32-39
	No:	Claims	1-3,8,9,11,18,28,29,31,40
Inventive step (IS)	Yes:	Claims	4-7,10,12-17,19-27,30,32-39
	No:	Claims	33-36
Industrial applicability (IA)	Yes:	Claims	1-40
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Article 33(2) PCT

The document EP-A-0 117 768 (D1) discloses in Claim1 a polyurethane hydrogel, characterized in that it is essentially constituted by a polyurethane of polyethylene oxide obtained by a crosslinking reaction by a polyfunctional isocyanate effected on the polyethylene oxide in solution in a non-aqueous solvent. D1 discloses in Example 8 the stoichiometric composition of the following reacting mixture: - polyethylene oxide 2000, 20 g (0.01 moles); -trimethylolpropane, 1 g (0.0074 moles); - hexamethylene diisocyanate, 3.7 g (0.022 moles). The obtained material is transparent when it is swollen at equilibrium in dioxane. It remains transparent when the dioxane is exchanged with water. Thus, moulded at the appropriate form constitutes contact lenses of very good quality. On the basis of that disclosure the subject-matter of Claims 1-3, 9, 11, 28, 29, 31 and 40 is anticipated by D1.

The document WO-A-02/00749 (D2) discloses in Claim 1 a prepolymer prepared by reacting a mixture comprising (a) at least one multifunctional compound, (b) at least one diisocyanate, and (c) at least one diol, wherein said prepolymer, when reacted with an excess of water, forms a hydrogel polymer. Example 3 discloses that 100 grams of Carbowax 1450 (polyethylene oxide having a molecular weight of about 1500) (0.066 moles) and 4.47 grams of trimethylol propane (0.033 moles) were melted together and mixed with 43.7 grams of methylene dicyclohexyl diisocyanate (0.16 moles). This mixture was heated for about 100 hours at 79°C, during which time the measured free isocyanate content decreased from a starting value of 9.46% to 2.84%, which is the theoretical content for the prepolymer in which all hydroxyl groups have reacted with isocyanate. This prepolymer was mixed with water, and reacted during a period of about 5 minutes to form a hydrogel polymer having an equilibrium water content of about 70%. The mixture was poured into a mold to form a contact lens. On the basis of that disclosure the subject-matter of Claims 1-3, 8, 9, 11, 18, 28, 29, 31 and 40 is anticipated by D2.

The document US-A-4 886 866 (D3) discloses in Claim 1 a hydrophilic, biocompatible contact lense comprising a hydrated polyurea-urethane polymer derived from prepolymer units at least 75% of which are oxyethylene-based diols or polyols, said diols or polyols having essentially all of the hydroxyl groups capped with polyisocyanate. Example VIII discloses that a prepolymer was prepared by heating to 60°C a mixture of 0.04 moles homopolymer polyethylene glycol (approx. 8000 MW) and 0.02 moles trimethylolpropane. The preheated mixture was added to 0.10 moles

toluene diisocyanate over a period of about one hour, with stirring. After an additional hour of stirring, the isocyanate concentration reached a sustantially constant value of 0.20 meq/gm (theoretical =0.18 meq/gm). Polymerization to gel the prepolymer solution may be accomplished by contact with water to yield a polyurea-urethane polymer or with another crosslinking agent to yield a polyurethane polymer. Shaped gels are conveniently made in this manner (column 2, lines 57-62). On the basis of that disclosure the subject-matter of Claims 1-3, 8, 9, 11, 18, 28, 29, 31 and 40 is anticipated by D3.
Novelty is recognized for the subject-matter of Claims 4-7, 10, 12-17, 19-27, 30 and 32-39, since none of the prior art discloses said subject-matter.

Article 33(3) PCT
None of the prior art makes obvious the subject-matter of Claims 4-7, 10, 12-17, 19-27, 30, 32 and 37-39 of the present invention.
With regard to Claims 33-36, the document D3 discloses in Example VI that an antioxidant, Irganox 1076 was added to the reactants used to prepare the prepolymer. Since ascorbic acid and 2,6-ditertiarybutyl4-hydroxyanisole can be considered to be conventional antioxidants, the subject-matter of Claims 33-36 can be considered to be made obvious by the above disclosure in D3 in the absence of evidence of unexpected effect vis-à-vis the antioxidant Irganox 1076 used in D3.